BEFORE THE FEDERAL FOOD AND DRUG ADMINISTRATION

In Re:)
)
Misbranding of regulated drugs by Third Parties)
)

Date: 17 April, 2002

Dockets Management Branch, Food and Drug Administration, Department of Health and Human Services, Room 1-23, 12420 Parklawn Drive, Rockville, Maryland 20857.

CITIZEN PETITION

The undersigned submits this petition under Chapter III, Section 301 [331] of the Federal Food, Drug and Cosmetic Act or the Public Health Services Act or any other statutory provision for which authority has been delegated to the Commissioner for Food and Drugs under 21 CFR 5.10 to request the Commissioner of Food and Drugs to amend a regulation or take any other form of administrative action.

A. Action Requested

The Federal Food, Drug and Cosmetic Act, Chapter III, Section 301. [331] states that the following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded.
(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

This act is generally interpreted to regulate the activities of manufacturers of drugs. However, there is a lacuna in the law – one which Third Parties, who have an interest in promoting the sale of certain regulated drugs, are exploiting, quite unethically, we respectfully submit.

For example, during the calendar year 2001, the National Abortion Federation (NAF), a trade group for abortion clinics owners and operators, undertook a $30 million national branding campaign in national magazines, including *Self, People, Cosmopolitan,* inter alia. The branding campaign – designed to promote the use of the recently approved drug, RU-486, and its domestic brand, mfipristone – did not list the side effects of the drug. The side effects include, inter alia, vaginal bleeding. By not listing the side effects of the regulated drug, the branding campaign was designed to promote the drug as completely safe, and without side effects. In other words, it was deceptive and misleading and was not an accurate reflection of the brand.

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The executive director of the NAF, in an interview in the spring of 2001 with *The Wall Street Journal,* bragged that her organization did not have to list the side effects of the drug because it was "not a drug manufacturer."

WHEREFORE, Petitioner respectfully requests of the Honorable Food and Drug Administration the following action:

1) To investigate the misbranding of the National Abortion Federation, Planned Parenthood, and other groups whose members benefit from the sale of the regulated drug, RU-486, to determine the extent of their misbranding campaign;
2) To issue amend Section 301 [331] reigning in deceptive advertising or misbranding undertaken by Third Parties, who directly benefit from the sale of regulated drugs.
3) To refer the matter, with urgency, to any other federal regulatory body which has the authority to reign in this kind of deceptive commercial conduct.

Furthermore, Petitioner respectfully requests that the amended regulation, be worded as follows:

4) The following acts and the causing thereof are hereby prohibited:
   (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated, misbranded, or misleadingly promoted to the public;
   (b) The adulteration or misbranding or misleading promotion by manufacturers or any other party of any food, drug, device, or cosmetic in interstate commerce.

B. STATEMENT OF GROUNDS

The National Abortion Federation (NAF), a trade group for abortion clinics owners and operators, undertook a $30 million national branding campaign in national magazines, including *Self, People, Cosmopolitan,* inter alia. The branding campaign – designed to promote the use of the recently approved drug, RU-486, and its domestic brand, mfipristone – did not list the side effects of the drug. The side effects include, inter alia, vaginal bleeding.

By not listing the side effects of the regulated drug, the branding campaign was designed to promote the drug as completely safe, and without side effects. In other words, it was deceptive and misleading and was not an accurate reflection of the brand.

The executive director of the NAF, in an interview in the spring of 2001 with *The Wall Street Journal,* bragged that her organization did not have to list the side effects of the drug because it was "not a drug manufacturer."

The NAF's representatives made similar statements in other press interviews.

Other press stories published last year indicated that abortion clinics are responsible for 75 percent of the sales of RU-486. Thus, the members of the NAF benefit from their misleading advertising through enhanced sales.

Clearly, if the NAF were allowed to get away with this deceitful conduct, it would set an adverse precedent – and enable any Third Party group which benefits from the sale of regulated drugs. The list of such potential Third Party beneficiaries is seemingly endless.

Petitioner in August of 2002 filed a lawsuit for injunctive and declaratory relief in the Circuit Court of Cook County, Illinois, alleging violations of the Illinois Deceptive Trade Practices Act for its misbranding campaign. The suit received national publicity in *The Washington Times,* inter alia. The Petitioner in January, 2002, agreed to a joint dismissal of the suit, because of a lack of legal resources to pursue the matter.

Petitioner believes that the Honorable Food and Drug Administration is the only agency which has the power to reign in this deceptive conduct.

C. CERTIFICATION

The undersigned certifies that to the best knowledge and belief of the undersigned that this petition includes all information and views on which the petition relies and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Signature: Gene Koprowski

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Comments THIS IS OUR REVISED CITIZEN PETITION. THANK YOU FOR THE FAX OF 2-20-02.